



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/806,961

03/23/2004

Greg Marik

31132.195

2351

46333 7590 07/18/2008
HAYNES AND BOONE, LLP
901 Main Street
Suite 3100
Dallas, TX 75202

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

07/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,961	Applicant(s) MARIK ET AL.	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9, 11, 14-18, 24-26 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 11, 14-18, 24-26, and 29-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-39 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Zdeblick (US 2002/0082701 A1) does not disclose the center member being in articulating engagement with the members. The examiner disagrees. Zdeblick discloses that the center member is positioned between the members, but NOT interconnected thereto (P0072). Zdeblick further discloses preserving disc motion (P0078) and allowing three degrees of motion (P0105). The vertebrae moves in more directions than just a compressive direction, since the center member is elastic, it will move along with the movement of the vertebrae bones inherently, including bending, as the members are not fixed to one another. Zdeblick's member components move relative to one another, replacing the joint and providing articulation. Applicant seems to be interpreting the term "articulation" much more narrow than the words plain meaning. The applicant has also argued that Zdeblick does not disclose a second curvature smaller than the first curvature. The examiner disagrees. The first curvature seems to have a flatter curve than the first curvatures. Further, Zdeblick discloses the intermediate lobe (curve at the second and fourth curvature) to be adjustable to different widths, smaller or larger, and with a smaller width, the second curvature will inherently be smaller, see P0083 and P0112.

The applicant has argued that Judet (US 5,314,485) does not disclose an intervertebral implant. The examiner disagrees. Intervertebral implant is intended use language requiring only a device capable (sized and configured to fit) of placement into an intervertebral space. Judet's

Art Unit: 3738

device is capable of placement in such a location. There is not structure tied to the term "intervertebral implant". Judet discloses all structural limitations claimed and has the capability to perform the intended use thus meets the claim. Applicant is reminded that this is a product claim, thus where the implant is placed is not given patentable weight as this is a method of implantation step.

The applicant has argued that Sennwald et al. (US 5,507,821) does not disclose an intervertebral implant. The examiner disagrees. Intervertebral implant is intended use language requiring only a device capable (sized and configured to fit) of placement into an intervertebral space. Sennwald's device is capable of placement in such a location. There is not structure tied to the term "intervertebral implant". Sennwald discloses all structural limitations claimed and has the capability to perform the intended use thus meets the claim. Applicant is reminded that this is a product claim, thus where the implant is placed is not given patentable weight as this is a method of implantation step.

The applicant has argued that Casutt (US 2003/0045939 A1) does not disclose the center member in articulating engagement with the first and second members. The examiner disagrees. The center member is elastic and moves in response to forces placed on it from the vertebral bones. As the vertebrae moves, so does the center member, changing shape. As the vertebral bones compress the first and second members, the center member flattens out and portions of the middle of the center member move to the upper or lower surfaces, thus there is some sliding along the upper and lower surfaces of the center member upon compression as particles and portions of the composition reposition upon reaction to forces. Relative movement between the components is present as the device replaces the function of the natural joint. Articulation is

Art Unit: 3738

present. Applicant seems to be giving articulation a more narrow definition than its plain and ordinary meaning.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 9, 14-18, 24-25, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Zdeblick et al. (US 2002/0082701 A1, cited previously). See figure 16 and respective portions of the specification. Zdeblick discloses an implant (110) comprising a first member (112) comprising a concave recess (recess of first lobe see attachment 1) a second member (114) having a convex projection (intermediate lobe, see attachment 1) with a smaller radius than the concave recess (see fig. 16, intermediate lobe appears a bit narrower, thus has a smaller curvature, see also, P0083 and P0112 which disclose different sizing for the intermediate lobe, which inherently causes a change in curvature, the sizing being smaller or larger), and a center member (spacer 116) having a convex surface (first lobe of 116) for mating with the concave recess and a concave center portion (intermediate lobe of 116) and convex outer portion (first lobe of 116) to mate with the second member having similar curvatures, see attachment 1 cited in previous office action, the center member being in articulating engagement with the first and second members (motion is present, restores motion of disc; P0072, P0077, P0105). The lobes are disclosed to be partly cylindrical, thus have constant radii.

Art Unit: 3738

Claims 1-4, 7, 9, 11, 14-18, 24-26, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Judet (US 5,314,485, cited previously). Judet discloses an implant (1) comprising a first member (2) comprising a concave recess (23) a second member (4) having a convex projection (40) with a smaller radius than the concave recess (see fig.1, 2), and a center member (3) having a convex surface (barrel surface) for mating with the concave recess and a concave center portion (32) and convex outer portion (barrel surface) to mate with the second member having similar curvatures, the center member in articulating engagement with the first and second members. See figures 1 and 2 for remaining dependent claims.

Claims 1-4, 7, 9, 11, 14-18, 24-26, 29-34 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sennwald et al. (US 5,507,821). See figures 1, 2 and respective portions of the specification. Sennwald discloses an implant *capable of* placement in an intervertebral location comprising a first member (18) having a first concave curvature (5), a second member (1) having a convex second curvature smaller than the first (see fig.1), and a center member (2) having a convex third surface (4) similar to the first surface, and a fourth surface having a concave center portion (3) and outer convex portion (seen in dashed lines in fig.2) similar to the first, wherein the first and second members are able to translate relative one another. Sennwald discloses a sidewall connecting the third (4) and fourth (3) surface that is cylindrical (see figs.1, 2).

Claims 1, 7, 9, 14-18, 24-26, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Casutt (US 2003/0045939 A1). Casutt discloses an intervertebral implant (fig.1, 3) comprising a first member (2) having a first concave curvature (right or left recess of 2), a

Art Unit: 3738

second member (1) having a convex second curvature (middle protrusion) smaller than the first (see fig.1; first curvature appears to be flatter curve), and a center member (3) having a convex third surface (right or left convexity on the bottom of 3) similar to the first surface, and a fourth surface (top surface of 3) having a concave center portion (middle of 3) and outer convex portion (top surface of 3 on right or left) similar to the first, wherein the first and second members are able to translate relative one another and the center member in articulating engagement with the first and second members (motion is occurring relative the components thus has articulation as it replaces the natural movement of the disc).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casutt (US 2003/0045939 A1). Casutt discloses the intervertebral implant substantially as claimed however has shown the center member (and first and second members) to have a somewhat kidney shaped sidewall rather than a circular/cylindrical sidewall as claimed. The outer periphery of the device is kidney shaped instead of circular. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a circular/cylindrical periphery since such a modification would have involved a mere change in the shape of the component. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Circular peripheries are known in the art as alternatives to kidney shapes. It is noted that the term, "relatively rigid" is indefinite as it is a

Art Unit: 3738

relative term. The materials of Casutt (P0030) are solid materials after implantation and may be considered to have some rigidity as they harden from their first liquid state.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755.

The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738